CD4 COUNTS AND VIRAL LOAD MEASUREMENTS IN AIDS DRUG ASSISTANCE PROGRAM (ADAP): QUALITY (DATA) MANAGEMENT AND HEALTH INDICATORS

FEBRUARY 2004

ARNOLD SCHWARZENEGGER
Governor
State of California

S. Kimberly Belshé
Secretary
Health and Human Services Agency

Tom McCaffery
Chief Deputy Director
Department of Health Services

CD4 COUNTS AND VIRAL LOAD MEASUREMENTS IN AIDS DRUG ASSISTANCE PROGRAM (ADAP): QUALITY (DATA) MANAGEMENT AND HEALTH INDICATORS

Prepared by:

Dennis T. Wong, Ph.D.
Karen S. Fairgrieves, M.B.A.

Kevin Reilly, D.V.M., M.P.V.M.
Deputy Director
Prevention Services

Michael Montgomery
Chief
Office of AIDS

Juan Ruiz, M.D., Dr.P.H.
Acting Chief
HIV/AIDS Epidemiology Branch
Office of AIDS

February 2004

ACKNOWLEDGMENTS

We would like to thank Susan M. Sabatier and Kathleen Russell for providing valuable feedback on this report.

Correspondence
Please send any questions or comments to Dennis T. Wong: **dwong2@dhs.ca.gov.**

Suggested Citation
Wong, D.T., Fairgrieves, K.S., *CD4 Counts and Viral Load Measurements in AIDS Drug Assistance Program (ADAP): Quality (Data) Management and Health Indicators*. California Department of Health Services, Office of AIDS, 2004.

TABLE OF CONTENTS

TABLES

FIGURES

EXECUTIVE SUMMARY

Objectives. The objectives of this study were to: 1) assess the quality of health outcome data (CD4 counts and viral load) in ADAP; 2) develop a methodology to continuously monitor these measures on an annual basis; and 3) examine these health indicators of ADAP clients, presently and over time.

Design. Using clients enrolled in ADAP during fiscal year (FY) 2001-02, CD4 counts were screened based on three criteria: enrollment eligibility dates, lab values of test results, and the time between test dates and eligibility dates. This ensured the highest quality data. Three populations of interest were examined: overall ADAP population, 100 percent ADAP clients who do not have private insurance co-payments or Medi-Cal share-of-costs, and 100 percent ADAP clients who have CD4 counts over two years. Because test types were not available for viral load measures, this set of data was not screened and subjected to further analysis.

Results. The demographics of the three populations were similar on gender but differed on race/ethnicity. The two 100 percent ADAP populations had higher percentages of Hispanics/Latinos than others. Gender did not play a role in the distribution of CD4 counts in any of the populations but race/ethnicity differences emerged. Whites, African Americans, and Hispanics/Latinos all had CD4 counts greater than (GT) 350 than between 200–350 or less than (LT) 200. In the lower CD4 categories for the 100 percent ADAP clients, Whites were more frequent in the 200–350 group than the LT 200 group. However, African Americans and Hispanics/Latinos were more likely to have CD4 counts LT 200 than between 200–350. In the 100 percent ADAP population with two years of CD4 count data, 46 percent of clients with a baseline CD4 count LT 200 improved upon their CD4 category at the more recent test, 45 percent of clients with a baseline CD4 count between 200–350 improved to GT 350, and 50 percent of clients maintained their CD4 count in the GT 350 category. Confirming these findings, an alternative approach with a more sensitive measure found that 43 percent of ADAP clients increased their CD4 counts by 15 percent or more with an average change of +190. Thirty-three percent of clients maintained their CD4 counts.

Conclusions. These results showed the positive effect of ADAP on the population it serves over time. While race/ethnicity differences were found, it is important to note most clients in all groups had CD4 counts GT 350. When usable viral load data becomes available, ADAP will be better able to monitor the health outcomes of its clients along with deaths, hospitalizations, and co-morbidities to provide the clearest picture of how well ADAP benefits the clients it serves.

Background

California's ADAP, authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, provides HIV-related prescription drugs to uninsured and underinsured low- to moderate-income persons living with HIV/AIDS (PLWH/A). ADAP is coordinated throughout the state by 61 local health jurisdictions with over 250 enrollment sites and 892 enrollment workers.

At the enrollment sites, enrollment workers screen potential clients for ADAP eligibility. The eligibility requirements are:

- Resident of the State of California;
- HIV-infected;
- At least 18 years of age;
- Have a Federal Adjusted Gross Income below $50,000;
- Have a valid prescription from a licensed California physician; and
- Have limited or no prescription drug benefit from another source (private insurance co-payments or Medi-Cal share-of-cost).

As part of the initial enrollment process or annual recertification, each client provides demographic information such as gender, race/ethnicity, birth date, income level, and HIV/AIDS diagnosis. CD4 counts and viral load measurements have not been required for ADAP enrollment prior to FY 2003-04, but enrollment workers were encouraged to gather this data via client self-reporting and/or supporting laboratory documentation.

CD4 counts and viral load measurements provide measures of an individual's immune system. These are two indicators of the health status of PLWH/A, which help physicians decide when to initiate HIV drug therapy, what medications to start, when to change therapy, and what drug therapy to prescribe when changing regimens.

According to the supplemental report for women accompanying the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents,[1] females may have higher CD4 counts than males.[2] A meta-analytic review of 14 published studies, however, concluded that viral load measurements were lower in females than males with similar CD4 counts and stage of HIV disease.[3] Race/ethnicity differences may also occur in CD4 counts and viral load levels. In a study with antiretroviral naïve HIV-infected patients, Hispanics/Latinos had lower CD4 counts and higher viral load measurements than Whites. African Americans had lab values in-between those of

---

[1] United States (U.S.) Department of Health and Human Services, Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, July 14, 2003.
[2] U.S. Department of Health and Human Services, Considerations for Antiretroviral Therapy in Women, July 14, 2003.
[3] Napravnik, S., Poole, C., Thomas, J.C., Eron Jr., J.J., Gender Differences in HIV RNA Levels: A Meta-analysis of Published Studies. *J Acquir Immun Defic Syndr.* 2002;31:11-19.

Hispanics/Latinos and Whites.[4] The significance of these differences for both gender and race/ethnicity remains debatable.

The purpose of this study is three-fold:

1. Assess the quality of the data regarding CD4 counts and viral load;
2. Develop a methodology to continuously monitor these measures on an annual basis; and
3. Examine these health indicators of ADAP clients, presently and over time.

Methodology and Results

ADAP Population

In FY 2001-02, ADAP served 24,102 clients. Of these clients, 90 percent were male, 10 percent female, and less than 1 percent were other/unknown. The racial/ethnic breakdown was 44 percent White, 15 percent African American, 34 percent Hispanic/Latino, and 6 percent other/unknown. In terms of insurance coverage, 69 percent had no insurance, 19 percent had private insurance benefits, and 12 percent had Medi-Cal. ADAP will pay a client's private insurance co-payment, Medi-Cal share-of-cost, or pay for the full price of HIV/AIDS-related drugs if a client has exceeded their private insurance spending limit. Clients without private insurance, who do not qualify for Medi-Cal, and ADAP is their only payer for HIV/AIDS drugs, are considered 100 percent ADAP clients.

Quality Assessment

CD4 Counts

Prior to computing descriptive statistics for CD4 counts, the following variables were screened for accuracy (i.e., missing or unknown values and out-of-range values).

1. Eligibility Dates. An eligibility date indicates when a client's current annual ADAP eligibility started. One year after the eligibility start date, the client has 30 days in which to re-certify before becoming ineligible.

   Since eligibility lasts 13 months (one year plus a 30-day grace period), dates prior to July 2000 and after June 2002 were considered invalid for FY 2001-02. Ninety-eight percent of clients fell within the acceptable range (July 2000–June 2002). The remaining two percent were pre-July 2000, post-June 2002, or missing values (Table 1).

---

[4] Swindells, S., Cobos, D.G., Lee, N., et al., Racial/Ethnic Differences in CD4T Cell Count and Viral Load at Presentation for Medical Care and in Follow-up After HIV-1 Infection. *AIDS*. 2002;16(13) 1832-1834.

Table 1. Frequency and Percentage of Eligibility Dates		
Eligibility Date	**Statistic**	
	Frequency	**Percent**
Pre-July 2000	512	2.12%
July 2000 to June 2002	23,570	97.79%
Post-June 2002	14	0.06%
Unknown	6	0.02%
Total	24,102	100.00%

2. Lab Values. U.S. Department of Health and Human Services recommends the use of antiretroviral treatment for all symptomatic PLWH/A, or asymptomatic PLWH/A whose CD4 counts fall below 350 or viral load measurements are above 55,000 copies/ml.[5] (Many physicians treat HIV/AIDS aggressively and begin antiretroviral therapy when CD4 counts are GT 350 or viral loads are under 55,000.) When CD4 counts drop below 200, PLWH/A are at an increased risk of serious infection.

CD4 counts range from 500 to 1,500 for healthy persons.[6] Therefore, values GT 1,500 were considered invalid. Using this criterion, 99 percent of the CD4 values fell within the acceptable range for HIV/AIDS-infected individuals (Table 2). ADAP clients will be broken into three CD4 categories in accordance with treatment guidelines: LT 200, 200–350, and GT 350.

Table 2. Frequency and Percentage of CD4 Counts		
CD4 Count	**Frequency**	**Percent**
0-1,500	23,775	98.64%
1,501-2,000	61	0.25%
2,000+	68	0.28%
Unknown	198	0.82%
Total	24,102	100.00%

3. Test Dates. For PLWH/A, CD4 tests are generally recommended on a quarterly basis. The test date is important, because test results performed more than three to six months ago may not describe one's current level of health.

---

[5] U.S. Department of Health and Human Services, Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, July 14, 2003.
[6] Labs Tests Online at www.labtestsonline.org. Medical Essentials Health Information Zone at www.healthzone.co.za.

Historically, test results were considered invalid for ADAP reporting purposes if the test date was six months prior to the start of the reporting period. For example, in the FY 2000-01 Annual Report (July 1, 2000 to June 30, 2001), all test dates prior to January 1, 2000, were considered invalid. While this method was a reasonable way to screen data, it did not factor in eligibility start dates. That is, a November 1999 test date should be considered acceptable if the client's eligibility began in November 1999. Since the client's one-year eligibility would last until November 2000, the client would be included as a FY 2000-01 client even though the client did not reenroll in ADAP.

To account for the once a year enrollment/recertification, a six-month rule was used to further identify acceptable test dates. The test date must be no earlier than six months prior to the client's eligibility date and no later than 12 months after the eligibility start date. Difference scores were computed between test dates and eligibility dates (Table 3). For example, if a client's most recent CD4 test was taken in the same month as enrollment, the difference score would be zero (13 percent). If the test was taken one month prior to enrollment, then the score would be -1 (19 percent). Because clients may submit laboratory values after enrollment, positive scores are possible (1 percent).

Table 3. Time Between CD4 Test Date and Eligibility Date		
Difference (Months)	**Statistic**	
	Frequency	**Percent**
-13 or Less	4,801	19.92%
-10 to -12	1,184	4.91%
-7 to -9	932	3.87%
-4 to -6	**2,510**	**10.41%**
-1 to -3	**9,957**	**41.31%**
0	**3,026**	**12.55%**
1 to 3	**130**	**0.54%**
4 to 6	**50**	**0.21%**
7 to 9	**59**	**0.24%**
10 to 12	**52**	**0.22%**
13 or More	10	0.04%
Unknown	1,391	5.77%
Total	**24,102**	**100.00%**
Difference = Test Date – Eligibility Start Date		

Overall, 65 percent of the CD4 tests fell within the acceptable time frame. Consistent with HIV/AIDS guidelines, 54 percent of ADAP clients had tests performed three months prior to eligibility. However, 29 percent of clients had tests taken seven or more months prior to enrollment.

Viral Load

Viral load tests measure the amount of HIV virus there is in one's bloodstream. Lower numbers reflect healthier persons. There are two main types of tests for viral load. PCR test, the most common viral load measure, can detect the amount of HIV RNA in a sample ranging from 50–750,000 copies/ml plasma. Scores lower than 50 are considered undetectable. The bDNA test results, which have a different measurement scale, can detect 5 (ultra-sensitive) – 1.5 million copies. Due to the variance in test results, it is recommended that the same test type be continually used over time to test viral load.

Several concerns have lead to the suspension of the analysis of the viral load measurements for this report. Currently, ADAP does not capture the test type, making it difficult to categorize the test results. For example, PCR test results are approximately two to two and a half times the value of first generation bDNA tests. Adding to the difficulty, ADAP cannot record a viral load measurement of undetectable (levels below the particular viral load detection capability).

Viral load would have been assessed in the same manner as CD4 counts. Eligibility dates and results would remain the same regardless of CD4 counts or viral load. The lab value breakdown of viral load measurements, based on treatment guidelines, would have been less than 1,500; 1,501-7,000; 7,001-20,000; 20,001-55,000; and GT 55,000. Final future screening would involve computing difference scores between viral load test dates and eligibility dates.

Final CD4 Analysis

To be considered to have a valid CD4 count, a client's test must meet all three criteria:

1. The eligibility date must be between July 2000 and June 2002;
2. The CD4 count must be between 0 and 1,500; and
3. The lab test must have been performed no more than 6 months prior and 12 months after the client's eligibility start date.

There were three ADAP populations of interest:

1. The overall ADAP population that reflects clients "as a whole." This group includes ADAP clients with private insurance or Medi-Cal as well as those clients who depend solely on ADAP for their HIV/AIDS drugs.
2. One hundred percent ADAP clients who do not have private insurance or Medi-Cal.
3. One hundred percent ADAP clients who have valid CD4 counts over the past two years.

For each population, the following relationships were analyzed:

- Total population and CD4 counts;
- CD4 counts within and between each race/ethnicity; and
- CD4 counts within and between each gender.

ADAP categorizes race/ethnicity into seven main groups: White, African American, Hispanic/Latino, Asian, Native American/Indian, Pacific Islander, and Multi-Racial/Ethnic. Asian, Native American/Indian, Pacific Islander, and Multi-Racial/Ethnic groups combined comprise six percent of the ADAP population. The low populations of these groups did not lend themselves to statistical analysis and were combined in the following tables. The analyses for this report focused on Whites, African Americans, and Hispanics/Latinos due to their higher populations.

1. Overall ADAP Population. Applying the three screening criteria to the overall ADAP population resulted in 15,473 clients (64 percent) with valid CD4 counts (see bottom of Table 4). A chi-square test of independence indicated the frequency of clients differed between CD4 count categories, $\chi^2 (2) = 2,47$, $\underline{p}=.000$. $\underline{Z}$-tests for proportions found that more clients had CD4 counts in the GT 350 category (52 percent) than in the 200–350 category (23 percent) and LT 200 category (25 percent).[7] Also, fewer clients had CD4 counts between 200–350 than below 200. Appendix A shows the $\underline{z}$-tests for comparing all of the individual cell frequencies. In contrast to the overall population, no relationship was found between gender and CD4 count, $\chi^2 (2) = 4,19$, $\underline{p}=.12$.

	CD4 Count Category						**Total**	**Percent**
Gender	**LT 200**	**Percent**	**200–350**	**Percent**	**GT 350**	**Percent**		
Male	3,493	25.25%	3,165	22.88%	7,174	51.87%	13,832	89.39%
Female	380	23.63%	351	21.83%	877	54.54%	1,608	10.39%
Other/Unknown	13	39.39%	6	18.18%	14	42.42%	33	0.21%
Total or Pct	**3,886**	**25.11%**	**3,522**	**22.76%**	**8,065**	**52.12%**	**15,473**	**100.00%**

Table 4.
CD4 Counts by Gender for Overall ADAP Population

A significant relationship was found between race/ethnicity and CD4 count, $\chi^2 (4) = 85.07$, $\underline{p}=.000$ (Table 5). Within group comparisons examine the same race but different categories (LT 200 Whites versus GT 350 Whites). Between group comparisons examine different races/ethnicities but the same category (GT 350 Whites versus GT 350 African Americans). Of particular interest, within race/ethnicity groups, both African Americans and Hispanics/Latinos had more clients in the LT 200 category (29 and 27 percent, respectively) than the 200–350

---

[7] Similar to chi-square tests, $\underline{z}$-tests are sensitive to large sample sizes such that small differences can be statistically significant.

range (20 and 24 percent). However, no difference was found for Whites between these two categories (22 versus 23 percent).

Between race/ethnicity groups, there was a higher proportion of Whites with CD4 counts GT 350 (56 percent) when compared to African Americans (51 percent) and Hispanics/Latinos (49 percent). Also, there were fewer Whites in the LT 200 category (22 percent) than the other races/ethnicities (29 and 27 percent).

Table 5.
CD4 Count by Race/Ethnicity for Overall ADAP Population

Race/Ethnicity	CD4 Count Category						Total	Percent
	LT 200	Percent	200–350	Percent	GT 350	Percent		
White	1,466	21.80%	1,516	22.55%	3,742	55.65%	6,724	43.46%
African American	628	28.89%	440	20.24%	1,106	50.87%	2,174	14.05%
Hispanic/Latino	1,524	27.19%	1,325	23.64%	2,757	49.18%	5,606	36.23%
Other	112	27.52%	111	27.27%	184	45.21%	407	2.63%
Unknown	156	27.76%	130	23.13%	276	49.11%	562	3.63%
Total or Pct	**3,886**	**25.11%**	**3,522**	**22.76%**	**8,065**	**52.12%**	**15,473**	**100.00%**

2. <u>One Hundred Percent ADAP Clients</u>. Of the overall ADAP population meeting the screening criteria, 60 percent of these clients were solely funded by ADAP (i.e., 100 percent ADAP with no private insurance co-payments or Medi-Cal share-of-cost benefits). A larger percentage of Hispanics/Latinos appeared in this group (48 percent) than in the overall population (36 percent) and in comparison to 100 percent ADAP clients who were White (32 percent) and African American (15 percent), because an undocumented status may prevent them from receiving Medi-Cal benefits that are available to the other groups.[8]

As with the overall population, the difference in proportions between CD4 count categories was significant, χ^2 (2) = 1,86, <u>p</u>=.000 (see bottom of Table 6). <u>Z</u>-tests indicated the number of clients in the GT 350 category (54 percent) was nearly double each of the other two CD4 categories (23 percent each), but there was no difference between the 200–350 and LT 200 categories. As with the overall population, there were no differences between gender and CD4 counts, χ^2 (2) = .308, <u>p</u>=.857.

---

[8] Morin, S.F., Kahn, J.G., Richards, T.A., Palacio, H. Eliminating Racial and Ethnic Disparities in HIV Care: The California Report. San Francisco (CA): AIDS Policy Research Center and Institute for Health Policy Studies and AIDS Research Institute, University of California, San Francisco, Policy Monograph Series—March 2000.

	CD4 Count Category						Total	Percent
Gender	**LT 200**	**Percent**	**200–350**	**Percent**	**GT 350**	**Percent**	**Total**	**Percent**
Male	1,899	23.17%	1,854	22.62%	4,443	54.21%	8,196	87.43%
Female	270	23.46%	252	21.89%	629	54.65%	1,151	12.28%
Other/Unknown	9	33.33%	5	18.52%	13	48.15%	27	0.29%
Total or Pct	**2,178**	**23.23%**	**2,111**	**22.52%**	**5,085**	**54.25%**	**9,374**	**100.00%**

Table 6.
CD4 Counts by Gender for 100 Percent ADAP Population

Consistent with the overall population results, race/ethnicity was found to have a significant relationship with CD4 counts within each group, $\chi^2(4) = 99.43$, p=.000 (Table 7). Except for Hispanics/Latinos, differences were found comparing all three CD4 categories within each race/ethnicity. Hispanics/Latinos were equally likely to have CD4 counts in the 200–350 and LT 200 categories, but they were also twice as frequent to have CD4 counts GT 350 than in the lower categories. Whites had more clients in the 200–350 than in the LT 200 category, but African Americans had more clients in the LT 200 than in the 200–350 category.

Between groups, both African Americans and Hispanics/Latinos were significantly more frequent in the LT 200 group than Whites. In contrast, a larger percentage of Whites were in the GT 350 group than African Americans and Hispanics/Latinos. All races were equally likely to fall into the 200–350 CD4 category.

	CD4 Count Category						Total	Percent
Race/Ethnicity	**LT 200**	**Percent**	**200–350**	**Percent**	**GT 350**	**Percent**	**Total**	**Percent**
White	517	17.42%	648	21.83%	1,803	60.75%	2,968	31.66%
African American	359	26.24%	278	20.32%	731	53.44%	1,368	14.59%
Hispanic/Latino	1,155	25.87%	1,040	23.30%	2,269	50.83%	4,464	47.62%
Other	63	26.14%	73	30.29%	105	43.57%	241	2.57%
Unknown	84	25.23%	72	21.62%	177	53.15%	333	3.55%
Total or Pct	**2,178**	**23.23%**	**2,111**	**22.52%**	**5,085**	**54.25%**	**9,374**	**100.00%**

Table 7.
CD4 Counts by Race/Ethnicity for 100 Percent ADAP Population

3. <u>One Hundred Percent ADAP Clients who have Valid CD4 Counts in the Past Two Years</u>. Comparing past and current CD4 counts allow for the interpretation of an individual's health history. Presumably, someone with an increasing CD4 count over time can be considered to have improving health and a suppression of HIV. It can be assumed that one is responding well to their drug regimen if their CD4 increases over time. Since reporting CD4 counts to ADAP was voluntary in FY 2001-02, a two-year history of CD4 counts was not available for all clients. To be included for this analysis, a client must have a valid CD4 count 6 to 24 months prior to the valid

FY 2001-02 CD4 test date. Six months was chosen as the minimum requirement to prevent two test dates from being taken too close together. Twenty-four months was the maximum requirement to allow for clients with their first test date at the beginning of their eligibility and their second test date at the end of their next year of eligibility. Of the 9,374 clients who met the three requirements and were 100 percent ADAP, 5,401 clients had a prior CD4 test on file and nearly 85 percent of these earlier tests met the 6-24 month requirement (Table 8.)

Table 8. Time Between Baseline and Most Recent CD4 Test Date		
Difference (Months)	**Statistic**	
	Frequency	**Percent**
> 38 months	50	0.93%
33-38 months	43	0.80%
25-32 months	485	8.98%
19-24 months	1,085	20.09%
13-18 months	1,706	31.59%
6-12 months	1,792	33.18%
1-5 months	168	3.11%
Invalid date	72	1.33%
Total	**5,401**	**100.00%**
Difference = Most Recent Test Date – Baseline Test Date		

Next, the most recent CD4 counts of these clients were examined to ensure the two-year clients were not a biased sample and comparable to either the overall population and 100 percent ADAP clients. The relationship between the distribution of client frequencies in CD4 categories was significant again, $x^2 (2) = 1,88$, $p=.000$ (see bottom of Table 9). Total clients in GT 350 category (63 percent) were more than twice as frequent than the other two categories (22 and 15 percent). There were also more clients in the 200–350 range than have a CD4 count LT 200. As with the other two populations, there was no difference in CD4 counts between males and females, $x^2 (2) = 2.89$, $p=.289$ (Table 9).

Table 9. Most Recent CD4 Counts by Gender for 100 Percent ADAP Clients with Two Years of Tests							
Gender	**CD4 Count Category**						**Total**	**Percent**
	LT 200	**Percent**	**200–350**	**Percent**	**GT 350**	**Percent**	**Total**	**Percent**
Male	599	14.98%	882	22.06%	2,517	62.96%	3,998	87.75%
Female	74	13.58%	109	20.00%	362	66.42%	545	11.96%
Other/Unknown	4	30.77%	2	15.38%	7	53.85%	13	0.29%
Total or Pct	**677**	**14.86%**	**993**	**21.80%**	**2,886**	**63.35%**	**4,556**	**100.00%**

Race/ethnicity continued to be a significant factor in the distribution of CD4 counts, x^2 (4) = 27.62, p=.000. Z-tests for the three CD4 categories within each racial/ethnic group indicated a significant difference among all CD4 groups with one exception (Table 10). There was no difference in the proportion of African Americans having a CD4 count of LT 200 or in the 200–350 range. For Whites and Hispanics/Latinos in the below 350 categories, fewer clients had CD4 counts LT 200 than between 200–350. All race/ethnicity groups were most likely to have a CD4 count of GT 350.

The number of differences between race/ethnicity groups slightly diminished in this study group probably due to low sample sizes. The only significant differences were between Whites and Hispanics/Latinos in the LT 200 and GT 350 CD4 categories. Whites were more likely than Hispanics/Latinos to have a CD4 count GT 350 but less likely to have a CD4 count LT 200. There was no difference in the number of Whites or Hispanics/Latinos who had a CD4 count between 200–350. There were also no differences among CD4 categories between African Americans and Whites or Hispanics/Latinos.[9]

| Table 10. Most Recent CD4 Counts by Race/Ethnicity for 100 Percent ADAP Clients with Two Years of Tests							
Race/Ethnicity	**CD4 Count Category**						**Total**	**Percent**
	LT 200	**Percent**	**200–350**	**Percent**	**GT 350**	**Percent**	**Total**	**Percent**
White	161	11.61%	285	20.55%	941	67.84%	1,387	30.44%
African American	86	16.67%	91	17.64%	339	65.70%	516	11.33%
Hispanic/Latino	399	16.46%	548	22.61%	1,477	60.93%	2,424	53.20%
Other	12	12.24%	37	37.76%	49	50.00%	98	2.15%
Unknown	19	14.50%	32	24.43%	80	61.07%	131	2.88%
Total or Pct	**677**	**14.86%**	**993**	**21.80%**	**2,886**	**63.35%**	**4,556**	**100.00%**

---

[9] Although the percentage of African Americans and Hispanics/Latinos were comparable in the LT 200 category, Whites and African Americans did not significantly differ as did White and Hispanics/Latinos due to the small sample size in African Americans.

With two CD4 tests available, observations could be made to determine if ADAP was improving the health of its clients. A breakdown of the baseline or earlier CD4 tests shows that 19 percent of clients had CD4 counts LT 200, 23 percent were in the 200–350 range and 58 percent were GT 350 (Figure 1). Comparing these percentages with the most recent CD4 tests shows that more clients had CD4 counts GT 350 after receiving ADAP assistance (Figure 2).

Figure 1.
Baseline CD4 Test Results
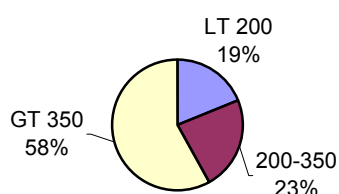
Figure 2.
Recent CD4 Test Results
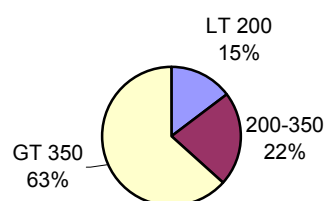
There were 867 clients with a CD4 count LT 200 on their baseline CD4 test. Nearly half of these clients showed an improvement in their CD4 counts with their most recent CD4 test with 32 percent moving to the 200–350 category and 14 percent having CD4 counts GT 350 (Table 11). For those clients with a CD4 count between 200–350 on their earlier test, 45 percent improved their CD4 counts to a GT 350 level while 13 percent fell to a CD4 count LT 200. Of the 2,621 clients with CD4 counts GT 350, 87 percent stayed above a 350 CD4 count on their second test, ten percent fell between 200–350, and only three percent fell below 200.

Table 11.
CD4 Count Changes Between Baseline and Recent Test

Recent CD4 Count Category	Earlier CD4 Count Category						Total	Percent
	LT 200 Percent	Percent	200-300 Percent	Percent	GT 350 Percent	Percent		
LT 200	465	53.63%	142	13.30%	70	2.67%	677	14.86%
200–350	280	32.30%	446	41.76%	267	10.19%	993	21.80%
GT 350	122	14.07%	480	44.94%	2,284	87.14%	2,886	63.35%
Total	**867**	**100.00%**	**1,068**	**100.00%**	**2,621**	**100.00%**	**4,556**	**100.00%**

As an alternative approach to assess client's improvement in CD4 counts over time, the same method of analysis as applied by a Houston Eligible Metropolitan Area (EMA)

Title I outpatient medical care facility was adopted.[10] A change in CD4 count was defined as a 15 percent difference from the baseline measurement. Thus, an increased CD4 count was +16 percent or more, maintained CD4 counts were +15 percent to –15 percent, and decreased CD4 counts were –16 percent or more (see Table 12). This is a more sensitive test of change, because the previous method using Table 11 results cannot detect an improvement for clients with baseline CD counts GT 350.

Group	Increased CD4 Count			Maintained CD4 Count			Decreased CD4 Count			Total
	Number	Avg. Change	Percent	Number	Avg. Change	Percent	Number	Avg. Change	Percent	
Male	1,727	189	43%	1,349	36	34%	921	188	23%	3,997
Female	249	198	46%	161	40	30%	135	178	25%	545
Other/ Unknown	5	186	38%	5	32	38%	3	44	23%	13
White	528	202	38%	507	38	37%	352	199	25%	1,387
African American	227	199	44%	166	41	32%	123	200	24%	516
Hispanic/ Latino	1,117	184	46%	773	35	32%	533	175	22%	2,423
Total	1,981	190	43%	1,515	36	33%	1,059	186	23%	4,555

**Table 12.
Alternative Approach to CD4 Changes Over Time**

Since these analyses were exploratory in nature, no statistical tests were performed. Overall, 76 percent of ADAP clients increased (43 percent) or maintained (33 percent) their CD4 counts, while 23 percent experienced a decrease in CD4 counts. This pattern was similar for gender except that more females increased their CD4 counts than males and more males maintained their CD4 counts than females. For race/ethnicity, Whites were equally likely to increase or maintain their CD4 counts, while more African Americans and Hispanics/Latinos increased their CD4 counts than maintained them.

Discussion

A methodology was developed to assess the quality of ADAP's CD4 count and viral load data. In FY 2001-02, the vast majority of clients (99 percent) self reported their CD4 status with 64 percent doing so within the timeframe criteria established for this study. In each study population, the majority of clients had a CD4 count GT 350. Interestingly, the overall population was more likely to have a CD4 count LT 200 than between 200–350. In the 100 percent ADAP population, clients were just as likely to

---

[10] Data examples from Ryan White CARE Act Data Support (CPDCMS) at www.careactdatasupport.hrsa.gov/archived/examples.htm.

have a CD4 count LT 200 as they were to be in the 200–350 group. When the 100 percent ADAP population was narrowed down to those having earlier CD4 counts available, these clients were more likely to have a CD4 count in the 200–350 range than in the LT 200 group.

The demographics of the three populations were similar on gender but differed on race/ethnicity. The two 100 percent ADAP populations had higher percentages of Hispanics/Latinos than Whites or African Americans possibly due to an undocumented status. Regardless, gender did not play a role in the distribution of CD4 counts in any of the populations. However, race/ethnicity differences in CD4 counts emerged. Within race/ethnicity, the majority of Whites, African Americans, and Hispanics/Latinos all had CD4 counts GT 350. In the lower CD4 categories for the 100 percent ADAP clients, for example, Whites were more frequent in the 200–350 group than the LT 200 group. However, African Americans and Hispanics/Latinos were more likely to have CD4 counts LT 200 than between 200–350. Between race/ethnicity groups in all populations, Whites were more likely to have higher CD4 counts (GT 350) than both African Americans and Hispanics/Latinos. Also, Whites were less likely to have a CD4 count LT 200 than others. While Hispanics/Latinos were more frequent in the 100 percent ADAP groups, the results were still similar across populations.

In the 100 percent ADAP population with two years of CD4 count data, 46 percent of clients with a baseline CD4 count LT 200 improved upon their CD4 category at the more recent test, 45 percent of clients with a baseline CD4 count between 200–350 improved to GT 350, and 50 percent of clients maintained their CD4 count in the GT 350 category. Confirming these findings, an alternative with a more sensitive measure found that 43 percent of ADAP clients increased their CD4 counts by 15 percent or more with an average change of 190. <u>These results show the positive effect of ADAP on the population it serves</u>.

In order to continually examine health indicators of ADAP clients, our research methodology will be applied towards future years of CD4 count and viral load data. In FY 2003-04, the self-reporting of CD4 counts and viral load measurement may become mandatory for client enrollment. Currently, ADAP is exploring the possibility of obtaining actual laboratory test results rather than relying on client self-report data.

Since the majority of ADAP clients had CD4 counts over 350, adding the categories of 350–500, 500–750, and GT 750 may provide additional insight into the overall health of clients. Adding viral load measurements once test type and undetectable status become available will be very useful to understanding the health status of ADAP clients.

Our goal is to monitor the health outcomes of our ADAP program by matching client variables (the types and amounts of antiretroviral drugs accessed with baseline CD4 counts and viral load measures) with outcome variables (changes in CD4 counts and viral load along with the frequency of deaths, hospitalizations, and co-morbidities). Collectively, all of this information will provide the clearest picture of how well ADAP benefits the clients it serves.

Appendix

Z-Test by CD4 Count: All Clients

COMPARISON			z	p
GT 350	vs.	200-350	44.87	.000
GT 350	vs.	LT 200	40.17	.000
200-350	vs.	LT 200	-4.23	.000
Significance based on p<.017.				

Z-Test by CD4 Count: 100% ADAP

COMPARISON			z	p
GT 350	vs.	200-350	37.61	.000
GT 350	vs.	LT 200	36.45	.000
200-350	vs.	LT 200	-1.02	.306
Significance based on p<.017.				

Z-Test by CD4 Count: 100% ADAP with Two Years

COMPARISON			z	p
GT 350	vs.	200-350	34.01	.000
GT 350	vs.	LT 200	44.25	.000
200-350	vs.	LT 200	7.78	.306
Significance based on p<.017.				

Note: To maintain an alpha level at .05, we used a Bonferroni adjustment based on the number of pair-wise comparisons per variable of interest (e.g., .05 / 3 = .017).

Appendix - Continued

Z-Tests for Race By CD4 Count: All Clients				
GROUP	COMPARISON		z	p
WITHIN RACES	W/GT 350	vs. W/200-350	33.11	.000
	W/GT 350	vs. W/LT 200	34.17	.000
	W/200-350	vs. W/LT 200	0.92	.360
	AA/GT 350	vs. AA/200-350	18.18	.000
	AA/GT 350	vs. AA/LT 200	11.84	.000
	AA/200-350	vs. AA/LT 200	-5.78	.000
	HL/GT 350	vs. HL/200-350	23.49	.000
	HL/GT 350	vs. HL/LT 200	19.47	.000
	HL/200-350	vs. HL/LT 200	-3.73	.000
BETWEEN RACES	W/GT 350	vs. AA/GT 350	3.89	.000
	W/GT 350	vs. HL/GT 350	7.17	.000
	AA/GT 350	vs. HL/GT 350	1.34	.180
	W/200-350	vs. AA/200-350	2.26	.024
	W/200-350	vs. HL/200-350	-1.43	.153
	AA/200-350	vs. HL/200-350	-3.21	.001
	W/LT 200	vs. AA/LT 200	-6.77	.000
	W/LT 200	vs. HL/LT 200	-6.94	.000
	AA/LT 200	vs. HL/LT 200	1.51	.132
Significance based on p<.0027.				

Note: To maintain an alpha level at .05, we used a Bonferroni adjustment based on the number of pair-wise comparisons per variable of interest (e.g., .05 / 18 = .0027).

Appendix - Continued

GROUP	COMPARISON		z	p
Z-Tests for Race By CD4 Count: 100% ADAP				
WITHIN RACES	W/GT 350	vs. W/200-350	25.82	.000
	W/GT 350	vs. W/LT 200	30.63	.000
	W/200-350	vs. W/LT 200	3.85	.000
	AA/GT 350	vs. AA/200-350	15.46	.000
	AA/GT 350	vs. AA/LT 200	11.83	.000
	AA/200-350	vs. AA/LT 200	-3.22	.001
	HL/GT 350	vs. HL/200-350	-15.33	.000
	HL/GT 350	vs. HL/LT 200	19.86	.000
	HL/200-350	vs. HL/LT 200	-2.46	.014
BETWEEN RACES	W/GT 350	vs. AA/GT 350	4.54	.000
	W/GT 350	vs. HL/GT 350	8.42	.000
	AA/GT 350	vs. HL/GT 350	1.69	.091
	W/200-350	vs. AA/200-350	1.13	.259
	W/200-350	vs. HL/200-350	-1.48	.140
	AA/200-350	vs. HL/200-350	-2.30	.021
	W/LT 200	vs. AA/LT 200	-6.73	.000
	W/LT 200	vs. HL/LT 200	-8.55	.000
	AA/LT 200	vs. HL/LT 200	0.27	.785

Significance based on $p<.0027$.

Note: To maintain an alpha level at .05, we used a Bonferroni adjustment based on the number of pair-wise comparisons per variable of interest (e.g., .05 / 18 = .0027).

Appendix - Continued

GROUP	COMPARISON		z	p
Z-Tests for Race By CD4 Count: 100% ADAP with Two Years				
WITHIN RACES	W/GT 350	vs. W/200-350	21.68	.000
	W/GT 350	vs. W/LT 200	30.29	.000
	W/200-350	vs. W/LT 200	5.95	.000
	AA/GT 350	vs. AA/200-350	14.07	.000
	AA/GT 350	vs. AA/LT 200	14.58	.000
	AA/200-350	vs. AA/LT 200	0.38	.707
	HL/GT 350	vs. HL/200-350	22.74	.000
	HL/GT 350	vs. HL/LT 200	28.85	.000
	HL/200-350	vs. HL/LT 200	4.87	.000
BETWEEN RACES	W/GT 350	vs. AA/GT 350	0.89	.375
	W/GT 350	vs. HL/GT 350	4.26	.000
	AA/GT 350	vs. HL/GT 350	2.02	.043
	W/200-350	vs. AA/200-350	1.42	.156
	W/200-350	vs. HL/200-350	-1.48	.139
	AA/200-350	vs. HL/200-350	-2.49	.013
	W/LT 200	vs. AA/LT 200	-2.92	.004
	W/LT 200	vs. HL/LT 200	-4.07	.000
	AA/LT 200	vs. HL/LT 200	0.12	.909
Significance based on p<.0027.				

Note: To maintain an alpha level at .05, we used a Bonferroni adjustment based on the number of pair-wise comparisons per variable of interest (e.g., .05 / 18 = .0027).